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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,264	03/07/2006	Laurie Anne Winter	38523.000324	7366

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EXAMINER

GANGLE, BRIAN J

ART UNIT	PAPER NUMBER
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1645

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06/25/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/564,264	WINTER ET AL.
	Examiner	Art Unit
	Brian J. Gangle	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 09 January 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-71 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) _____ is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 1-71 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application
- 6) Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-22, drawn to methods for expressing mature SpeB, using a polycistronic plasmid which comprises a polynucleotide encoding SpeB pro-polypeptide and mature SpeB polypeptide.

Group II, claim(s) 23-29 and 70, drawn to methods for producing mature SpeB comprising expressing SpeB, solubilizing the polypeptide, refolding the polypeptide, and recovering the native mature SpeB.

Group III, claim(s) 30-34, drawn to methods of expressing mature SpeB polypeptide using a polycistronic plasmid comprising a polynucleotide encoding mature SpeB polypeptide and GroEL polypeptide.

Group IV, claim(s) 35-44, drawn to mature SpeB polypeptide.

Group V, claim(s) 45-49, drawn to methods of immunizing against *Streptococcus pyogenes* comprising administering mature SpeB polypeptide.

Group VI, claim(s) 50-52 and 65, drawn to polycistronic plasmids, and host cells comprising said plasmid, comprising polynucleotides encoding SpeB pro-polypeptide and mature SpeB polypeptide.

Group VII, claim(s) 53-55 and 66, drawn to plasmids, and host cells comprising said plasmid, comprising polynucleotides encoding SpeB pro-polypeptide and mature SpeB polypeptide.

Group VIII, claim(s) 56-58, 62-64, 67, and 39, drawn to polycistronic plasmids, and host cells comprising said plasmid, comprising polynucleotides encoding mature SpeB polypeptide and GroEL polypeptide.

Group IX, claim(s) 59-64, and 68-69, drawn to polycistronic plasmids, and host cells comprising said plasmid, comprising polynucleotides encoding mature SpeB polypeptide, GroEL polypeptide, and GroES polypeptide.

Art Unit: 1645

Group X, claim(s) 62-64, 69, and 71 drawn to polycistronic plasmids, and host cells comprising said plasmid, comprising polynucleotides encoding mature SpeB polypeptide and one or more of the polypeptides listed in claim 62.

Strain/chaperone Election Requirement Applicable to Groups I, II, and X

In addition, Groups I, II, and X, detailed above, read on patentably distinct strains and chaperone proteins. Each combination is patentably distinct because they are drawn to methods using strains and chaperone proteins with differing biochemical and immunological properties and a further restriction is applied to each Group. For Group I, applicant must elect a single bacterial strain. For Group II, applicant must elect a chaperone protein from claim 24. For Group X, applicant must elect a specific combination of chaperone proteins.

Applicant is advised that examination will be restricted to only the elected strains and/or chaperone proteins and should not be construed as a species election.

The inventions listed as Groups I-X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking Groups I-X appears to be a mature SpeB polypeptide.

However, Eriksson *et al.* (Infect. Immun., 71:211-217, 1/2003) disclose the SpeB protein (see abstract).

Therefore, the technical feature linking the inventions of Groups I-X does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the art.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.**

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102,

103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Gangle whose telephone number is (571) 272-1181. The examiner can normally be reached on M-F 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brian Gangle
AU 1645



ROBERT A. ZEMAN
PRIMARY EXAMINER